In re National Prescription Opiate Litigation: MDL 2804

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND PROPOSED TESTIMONY OF JAMES RAFALSKI AND CRAIG MCCANN

Summary Sheet of Concise Issues Raised

Motion Names: Defendants' Motion to Exclude the Opinions and Proposed Testimony of James Rafalski (Dkt # 1785-1)

Defendants' Motion to Exclude the Opinion and Proposed Testimony of Craig McCann (Dkt # 1783-1)[1]

Concise Description of Issues:

Defendants' motions to exclude the opinions and testimony of Mr. Rafalski and Dr. McCann should be denied for the following reasons.

1. Mr. Rafalski has adequately disclosed the bases for his opinions. Defendants assert that Mr. Rafalski is basing his opinion on undisclosed "legal guidance" from the DEA. This is incorrect. Mr. Rafalski's 186-page report sets forth in detail the basis for his opinions: publicly available statutory and regulatory materials, along with a review of the evidence in this case, and his extensive professional experience. The Sixth Circuit has repeatedly found the experience of DEA agents on the job sufficient basis for them to offer their opinions. *See e.g., United States v. Ham*, 628 F.3d 801 (6th Cir. 2011); *United States v. Lopez-Medina*, 461 F.3d 724 (6th Cir. 2006). Here, Mr. Rafalski is relying on his 39 years of law enforcement experience—including 13 years as a DEA diversion investigator—where he applied the DEA's regulatory regime to the SOM programs of registrants. This is exactly what he does in his expert report when he analyzes Defendants SOM programs, including by reviewing the internal documents produced by Defendants.

2. The methodologies Mr. Rafalski offers are reliable. Mr. Rafalski identifies five potential methodologies for screening suspicious orders for unusual size. One of these methodologies—the *Masters* methodology—was confirmed by the D.C. Circuit. Variations of the remaining methodologies *have been used by several of the Defendants themselves* at various times. Mr. Rafalski also assumes that if a Defendant fails to perform due diligence on a suspicious order, all subsequent orders by the registrant must be held, regardless of whether those orders would have been independently flagged by a suspicious order methodology. Defendants complain that this assumption has never been "used in the real world," but ignore that this common-sense assumption was validated by the DEA as well as by some of the Defendants. Defendants' arguments at any rate go to weight not admissibility, and, thus, are not proper Daubert grounds for exclusion.

[1] Because of the overlapping arguments raised in these motions, Plaintiffs are filing a single opposition brief and summary sheet addressing both motions.

3. There is no reason for Mr. Rafalski to review suspicious orders in order to support his opinions. Defendants repeatedly criticize Mr. Rafalski for failing to review and opine on specific suspicious orders. This type of review is not necessary. The opinion Mr. Rafalski is offering is that Defendants were obligated to investigate all suspicious orders, including those identified by Dr. McCann's analysis, prior to shipping them and failed to do so. Given this, Mr. Rafalski had no reason to determine whether these orders were in fact diverted after being shipped. When asked by defense counsel to express a view as to whether orders that should not have been shipped were necessarily diverted, Mr. Rafalski responded that the fact that an order was flagged as suspicious made it more probable than not that diversion could occur. Defendants cannot bootstrap testimony they elicited, and then distorted, to create a basis for excluding an opinion Mr. Rafalski has not given.

4. The fact that Defendants could have used an alternative to Plaintiffs' methodologies does not mean that these methodologies are unreliable. As explained above, all of these methodologies are a reliable means of identifying suspicious orders of unusual size, and Defendants offer no basis, other than sheer speculation, that another reliable method would have actually identified a significantly different set of orders.

5. The argument that Dr. McCann's analysis does not reflect any legal duties owed by Defendants is premised on an unreasonably narrow reading of the CSA and its applicable regulations. In both motions, Defendants essentially argue that unless a requirement is specifically enumerated in a regulation, it does not exist. This ignores that Defendants are broadly required to maintain effective controls against diversion under the CSA. In order to maintain such effective controls, a Defendant must design and operate a system to identify suspicious orders, report to DEA suspicious orders, and decline to ship a suspicious order unless, through due diligence, the Defendant can determine that the order is not likely to be diverted. Mr. Rafalski's report sets forth his opinion as to how Defendants breached these duties. Dr. McCann's analysis provides an estimate of the suspicious orders that Defendants would have identified had they employed a reliable methodology. Taken together, Mr. Rafalski's and Dr. McCann's expert reports establish that Defendants breached their legal duties, provide an estimate as to the magnitude of this breach, and are part of Plaintiffs' overall framework of causation and damages.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION	MDL 2804
OPIATE LITIGATION	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PLAINTIFFS' CONSOLIDATED MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CRAIG MCCANN AND JAMES RAFALSKI

July 31, 2019

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INTRODUCTION

Plaintiffs submit this memorandum in opposition to Defendants' Motion to Exclude the Opinions Offered by James Rafalski (Dkt. # 1900) and Defendants' Motion to Exclude the Opinions and Testimony of Craig McCann (Dkt. # 1783).[1] Mr. Rafalski and Dr. McCann provide valuable testimony on key issues in this litigation: the deficiencies of the suspicious order monitoring ("SOM") programs of Defendants and the magnitude of suspicious orders that would have been identified had Defendants had adequate SOM programs.

Mr. Rafalski is a Drug Enforcement Administration ("DEA") expert with extensive law enforcement experience relating to the distribution of controlled substances under the Controlled Substances Act ("CSA") and SOM programs. Based on his DEA and other law enforcement experience, he carefully assesses the SOM programs of each of several Defendants and identifies their serious flaws with regard to the maintenance of effective controls against diversion. He also describes five different methodologies that could have been used to identify potentially suspicious orders that should not have been shipped without further diligence.

Dr. McCann is an expert in data analysis and computation, with decades of experience processing, validating and analyzing large sets of data. He performed the complex but methodologically non-controversial task of analyzing ARCOS data, employing the five methodologies described by Mr Rafalski to quantify their outputs and generate estimates of the number of suspicious orders from the Distributor and Pharmacy Defendants that were shipped into Cuyahoga and Summit Counties (the "Bellwethers" or "Bellwether jurisdictions"). He identifies hundreds of thousands of

[1] As explained below, because of the overlapping arguments raised in these motions, Plaintiffs are filing a single opposition brief addressing both motions. Plaintiffs note that Defendants' motion addressed to Dr. McCann explicitly states that Defendants ae not challenging Dr. McCann's opinions relating to the reliability of ARCOS and Defendant transaction data. McCann Mot., Dkt. # 1783 at 2 n.4. Put another way, Defendants are not challenging Sections I – VIII and the related Appendices of the Original McCann report. In addition to his original report, Dr. McCann also submitted a First Supplement and Second Supplement to his Original Report. Unless otherwise noted, all references are to Dr. McCann's Original Report.

orders shipped into Summit and Cuyahoga Counties that would have been flagged under *any* of these metrics. Using Dr. McCann's results. Mr. Rafalski then concludes that Defendants' failure to maintain effective SOM programs led to an excess quantity of opioid pills flooding the illicit market in CT1 jurisdictions.

While Defendants purport to challenge the methodologies used by Mr. Rafalski and Dr. McCann, they fail to identify any actual flaw in those methodologies, other than the conclusions they generate, which Defendants claim to find "incredible." *See* Summary Sheet for Motion to Exclude the Opinions of James Rafalski. But Defendants' incredulity about Mr. Rafalski's *conclusions* is a matter for cross-examination, not exclusion. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595 (1993) ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.").

Moreover, nearly all of Defendants' challenges to the Rafalski and McCann opinions are based on mischaracterizations of their opinions and of the requirements of the CSA. As they have done elsewhere, Defendants continue to conflate "suspicious orders," a technical term with a defined meaning in the law, with orders likely to be diverted, a determination that can be made only after the due diligence Defendants failed to conduct. Mr. Rafalski and Dr. McCann offer opinions about the numbers of orders Defendants shipped that should have been flagged as "suspicious" under the law and should have triggered the due diligence investigations that Defendants never conducted. While they offer opinions about the number of orders that should not have been shipped without due diligence, they do *not* offer opinions about the number of orders that were in fact diverted, nor are they required to do so. Plaintiffs have other evidence that diversion in fact occurred; the opinions of Mr. Rafalski and Dr. McCann, showing the astonishingly high percentage of suspicious orders that were shipped without appropriate due diligence, show that Defendants did not have sufficient controls to prevent diversion, thereby predictably leading to a large quantity of opioids entering the illicit

market. Mr. Rafalski's opinion that the failure to maintain effective controls against diversion caused the diversion that actually occurred, which in turn was a cause of the opioid epidemic, is neither controversial nor methodologically flawed. Grounded in his experience as a DEA diversion investigator, these conclusions follow ineluctably from his examination of Defendants' deeply flawed SOM programs and their meager reporting of suspicious orders to the DEA, and from Dr. McCann's data analysis revealing the extent of the orders shipped that would have been detected by any of Mr. Rafalski's five metrics.

Defendants' motions attacking the work of Dr. McCann and Mr. Rafalski also appear to be based on the premise that there is no reliable way to determine which orders should have been flagged as suspicious—a peculiar position given Defendants' statutory and regulatory obligation to do exactly that. But Defendants' failure to perform their legal duties should not be used as a basis to deny the Court information about the number of suspicious orders Defendants should have identified and performed due diligence on prior to shipping. This is especially true because Mr. Rafalski does not purport to identify only a single method that all Defendants should have used, and Dr. McCann does not offer a single definitive number of "suspicious orders" that were shipped. Rather, Mr. Rafalski opines about a range of SOM programs that might have satisfied Defendants' obligations with respect to detecting suspicious orders of unusual size,[2] and Dr. McCann offers a range for the number of orders that were shipped in violation of Defendants' duties.[3] No greater precision is required, as it is not necessary for the fact-finder to determine the precise number of such orders; the ranges provided are relevant to the magnitude of the problem, to the likelihood of diversion in the Bellwethers, and to

[2] Mr. Rafalski does not opine, and Plaintiffs do not concede, that any of these metrics necessarily would have satisfied Defendants' obligations. To the extent that some or all of these algorithms significantly undercount "suspicious orders," the Rafalski/McCann analysis shows the large number of orders that would have been flagged even under an inadequate system and thus how far below the threshold of compliance Defendants' actual conduct fell.

[3] Defendants focus on the high end of this range, but Dr. McCann and Mr. Rafalski propose to offer opinions about the entire range produced by application of all of the identified metrics.

the connection between the failure to detect, report, and halt suspicious orders and the diversion that in fact occurred. Defendants' argument poses the untenable proposition that the more ways there were to identify suspicious orders, the less Plaintiffs should be allowed to provide evidence that Defendants failed to use any of them. But the trier of fact need not proceed in the dark when multiple reliable methodologies exist to identify the suspicious orders that Defendants failed to notice. Defendants' motions regarding Rafalski and McCann should be denied.[4]

LEGAL STANDARD

The legal standards applicable to these motions are set forth in Plaintiffs' *Daubert* Roadmap Brief and will not be repeated in detail here. Specifically applicable to this motion, Plaintiffs note that the Sixth Circuit has repeatedly found the experience of DEA agents on the job sufficient basis for them to offer opinion testimony. *See, e.g.*, *United States v. Ham*, 628 F.3d 801, 804 (6th Cir. 2011) ("this Court has consistently held that expert testimony by a law enforcement officer about the method of operation of drug dealers is admissible pursuant to Fed.R.Evid. 702"); *United States v. Lopez-Medina*, 461 F.3d 724, 742 (6th Cir. 2006) ("courts have overwhelmingly found police officers' expert testimony admissible where it will aid the jury's understanding of an area, such as drug dealing, not within the experience of the average juror"); *United States v. Jemison*, 310 F. App'x 866, 875–76 (6th Cir. 2009) (agent's "twenty-six years of experience with narcotics investigation qualified him to provide opinion testimony regarding the price, packaging, and distribution of cocaine and cocaine base").

FACTS

Defendants do not challenge the qualifications of either Mr. Rafalski or Dr. McCann to offer their opinions. Plaintiffs note, however, that Mr. Rafalski has 26 years of law enforcement experience, including 13 years of experience as a diversion investigator for the DEA. Report of James Rafalski,

[4] Defendants also contend that Mr. Rafalski failed to disclose the basis for his opinions. As discussed below, there is no merit to this argument and the bases for all of his opinions are fully and completely disclosed.

Dkt. # 2000-22 at 4, 7. He is knowledgeable about the federal laws and regulations governing the distribution of controlled substances, and has training and experience relating to suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders, and the due diligence required before shipping an order flagged as suspicious. *Id.* Mr. Rafalski has also participated in multiple major investigations and prosecutions. The experience and methods that Mr. Rafalski utilized in his prior investigations are the same that he is using for his expert report.

Dr. McCann is a data computation and analysis expert. He has over 25 years of experience receiving and extracting data, processing and validating data, and producing various statistical analyses. Report of Craig McCann, Dkt. # 2000-14 at 1-2. He has served as an expert or consultant in over 100 different cases. *Id.* at 97-107. He is the President of the Securities Litigation and Consulting Group ("SLCG") which was founded in 2000 to apply finance, economics, statistics and mathematics in litigation and consulting. Dr. McCann earned his Ph.D. in economics from the University of California at Los Angeles.

The Rafalski report provides a detailed discussion of the federal regulatory regime governing the distribution of controlled substances, a regulatory regime that he is extremely familiar with given his work for the DEA. *Id.* at 8-36. Based on the applicable regulatory requirements, and his background, Mr. Rafalski identifies key components that are generally needed to maintain effective controls against diversion. *Id.* at 36-40. Mr. Rafalski then discusses various screening methodologies that one could use to identify orders that are suspicious by virtue of unusual size. *Id.* at 40-46. Mr. Rafalski opines that the Six Month Trailing Average methodology (Methodology A) is a reliable methodology for screening orders of unusual size, a view endorsed by the D.C. Circuit. *See Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212-213 (D.C. Cir. 2017). He also identifies several methodologies that are similar to the ones that Defendants purportedly employed but failed to actually execute. Finally, Mr. Rafalski evaluates the SOM programs used by the different Defendants based

on the documents produced by these Defendants in discovery. Based on this review, Mr. Rafalski opines on whether these SOM programs complied with applicable regulatory requirements, including the adequacy of the due diligence performed by Defendants on suspicious orders.

Dr. McCann takes the various screening methodologies that Mr. Rafalski identifies in his report and applies them to the ARCOS data. Dr. McCann also makes various assumptions as directed by Mr. Rafalski. Based on this analysis, Dr. McCann provides Mr. Rafalski with an estimate for distributors and chain pharmacies of the number of orders that should have been flagged as suspicious, and held pending investigation, but that Defendants shipped to Summit and Cuyahoga Counties. Mr. Rafalski in turn incorporates these estimates into his report.[5] Dr. McCann's data analysis based on Mr. Rafalski's underlying methodologies are also relied upon by Professor David Cutler to determine the share of Distributor and Pharmacy misconduct that Professor Cutler utilizes in his three-step analysis to quantify the share of prescription opioid shipments resulting in harms to the Bellwether jurisdictions. *See* Pls.' Opp. to Defs.' Motion to Exclude David Cutler's Opinions and Proposed Testimony at Section II.C. In particular, Methodology A endorsed by Mr. Rafalski and the D.C. Circuit in *Masters* forms the basis of this particular aspect of Professor Cutler's methodology.

ARGUMENT

I. MR. RAFALSKI'S OPINIONS SHOULD NOT BE EXCLUDED

A. Mr. Rafalski Has Fully Disclosed the Bases for His Opinions

Defendants' first argument—that Mr. Rafalski's 186-page report fails to adequately disclose the bases for his opinions—is wrong. Defendants contend that the sole basis for Mr. Rafalski's opinion must be "legal guidance from the DEA" that he refused to disclose consistent with the *Touhy* restrictions on his testimony. *Id.* at 7-8. This argument is flawed on multiple levels.

[5] Mr. Rafalski's report in turn sets forth as illustrative examples the results for three of the distributors and two of chain pharmacies.

Mr. Rafalski's report more than adequately discloses the bases for his opinions, including his conclusions that Defendants failed to operate adequate SOM programs. Mr. Rafalski's report contains a detailed discussion of the applicable regulatory framework, including the CSA, applicable DEA regulations, applicable DEA guidance, relevant judicial decisions, DEA administrative enforcement actions, and even industry guidelines. *See* Rafalski Rep., Dkt. # 2000-22 at 8-36. Mr. Rafalski also has 39 years of law enforcement experience, including 13 years with the DEA, applying this framework to the anti-diversion and SOM programs of registrants. In addition, Mr. Rafalski's analysis of Defendants' SOM programs is supported by a detailed review of Defendants' own internal documents, including emails, audit reports, and other materials. *Id.* at 46-186. Mr. Rafalski devotes 140 pages of his report to this analysis, which Defendants completely ignore. Given this detailed grounding in the regulatory regime, the detailed analysis of Defendants' SOM programs, and Mr. Rafalski's substantial professional experience, the argument that the opinions in his report are based on nothing more than his "personal beliefs" or "undisclosed legal guidance from the DEA" is absurd. Rafalski Mot., Dkt. # 1900 at 8. Mr. Rafalski's opinions are supported by the regulatory authorities he discusses in his report, as well as his professional experience applying these authorities. His "personal opinions" are reliable and relevant precisely because they are grounded in his years of experience as a DEA diversion investigator, during which time he investigated countless registrants' compliance with the CSA and implementing regulations. *See Ham*, 628 F.3d at 804; *Lopez-Medina*, 461 F.3d at 742; *Jemison*, 310 F. App'x at 875–76.

Defendants also attempt to undercut Mr. Rafalski's opinions by mischaracterizing and selectively quoting from his deposition testimony. Defendants assert that there is an inconsistency between a legal requirement to halt all subsequent shipments after identifying a suspicious order unless the registrant first investigates and clears the suspicious order, and Mr. Rafalski's acknowledgement that DEA does not tell registrants whether they can ship a particular order. Rafalski Mot., Dkt. #

1900 at 8. But the DEA's refusal to do a registrant's job with respect to identifying suspicious orders cannot nullify the legal duty to investigate all suspicious orders and ensure that opioids are not being shipped to entities engaged in diversion. Defendants also assert that Mr. Rafalski admitted that his "key components" are not regulatory requirements, but rather exceed the requirements set forth in DEA regulations. *Id.* In fact, Mr. Rafalski testified that the "key components" are elements of an effective SOM program which is *required to maintain effective controls against diversion under the CSA*. James Rafalski Dep. (05/14/19), Dkt. # 1969-19 at 447:3-20. While DEA regulations do not mandate specific requirements, in Mr. Rafalski's experience, these are all components that should be present in a functioning SOM program. *Id.* at 442:6-9; 443:5-10. It is precisely the job of an expert with Mr. Rafalski's experience to state, based on that experience, what it takes for controls against diversion to be "effective." The authorities cited above concerning the admissibility of opinion testimony from DEA agents confirms that Mr. Rafalski's *opinions* about what makes a SOM program effective are reliable, relevant, and admissible.

Defendants also assert that Mr. Rafalski testified that the requirement for manufacturers to use chargeback data and prescription data was based on his "personal opinion," and nothing in the statute or regulations. Rafalski Mot., Dkt. # 1900 at 8. In fact, Mr. Rafalski testified that the requirement to use chargeback data was based on: (a) the 2017 Memorandum of Agreement between Defendant Mallinckrodt and the DEA[6] (Rafalski Dep., Dkt. # 1969-19 at 656:5-657:1; 657:18-658:2; 659:12-22; 660:25-661:20); (b) personal experience bringing administrative actions against registrants that possessed chargeback data but failed to use it (*Id.* at 646:9-22); (c) DEA's briefings with manufacturers (*Id.* at 649:15-651:21) and; (d) the DEA's 2007 letters to manufacturers advising that

[6] Ex. 1, MNK-T1_0000557100 (Administrative Memorandum of Agreement between U.S. Department of Justice, Drug Enforcement Administration, Mallinckrodt plc and Mallinckrodt LLC (July 10, 2017) ("AMOA")).

they were required to use "all relevant transaction information"[7] (*Id.* at 655:18-25).[8] Defendants assert that Mr. Rafalski admitted that there is no requirement that suspicious order reports and due diligence records be retained "forever." Rafalski Mot., Dkt. # 1900 at 8. Actually, Mr. Rafalski testified that it was DEA policy that if there is no documentation or a record of due diligence, then in the DEA's view, due diligence did not occur. James Rafalski Dep. (05/13/19), Dkt. # 1969-18 at 171:8-12; Rafalski Dep., Dkt. # 1969-19 at 518:22-519:3. Moreover, the need for documentation was a practical consequence of the need to maintain effective controls: without a historical record of due diligence a registrant cannot evaluate subsequent orders from the same customers or prove regulatory compliance to the DEA. Rafalski Dep., Dkt. # 1969-18 at 127:24-129:12.

Finally, the suggestion that Mr. Rafalski's adherence to the *Touhy* restrictions that the DOJ has placed on him somehow requires striking his expert report should be rejected. As set forth above, Mr. Rafalski's report makes clear that the bases for his opinions are publicly available statutory and regulatory materials, along with a detailed review of the evidence in this case, and his professional experience. The fact that he is restricted in terms of divulging non-public DEA information, *which is the same restriction imposed on multiple defense experts*, cannot require the striking of his opinions. This case is thus distinguishable from *Siemens v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269 (Fed. Cir. 2011), where an expert sought to rely on classified studies he conducted at Los Alamos. Notably, the *Siemens* court did not preclude that expert from testifying; rather it ruled that the expert could not rely on these studies to support his testimony. Here, Mr. Rafalski does not seek to rely on undisclosed legal advice and has adequately disclosed the bases for the opinions he does offer.[9]

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[7] *See, e.g.*, Ex. 2, MNK-T1_00002701069 (Dec. 27, 2007 letter to Mallinckrodt).

[8] As set forth in more detail below, Mallinckrodt agreed to utilize chargeback data to specifically identify suspicious orders in connection with the 2017 AMOA.

[9] Moreover, the limited scope of Mr. Rafalski's testimony on these matters may well be due to Defendants' own conduct. As with many of Defendants' experts, Mr. Rafalski was testifying pursuant to a *Touhy* authorization from the DOJ. Defendants failed to give notice to the DEA or the DOJ of Mr. Rafalski's deposition, and as a result government counsel was unable to attend. Had a representative of the DEA or the DOJ been present, he or she may have been willing to

B. Mr. Rafalski's Opinions Are Well Supported and Reliable

1. Mr. Rafalski's Opinions Are Based on the Applicable Law and Regulations as Well as His Experience

According to Defendants, Mr. Rafalski's opinions regarding a registrant's duty to halt subsequent shipments after identifying an initial suspicious order, his identification of "key components" of an effective SOM program, the use of chargeback and prescription data by manufacturers, and the need to document and retain due diligence reports have no basis in the CSA or DEA regulations. Rafalski Mot., Dkt. # 1900 at 8. This argument is based on an unreasonably narrow reading of the CSA and applicable regulations, and essentially turns the regulatory framework on its head. As explained in Mr. Rafalski's report, and as further elaborated in Plaintiffs' Memorandum in Support of Motion for Partial Summary Adjudication of Defendants' Duties under the Controlled Substances Act, the CSA imposes a broad standard—that registrants "maintain effective controls against diversion"—and requires the registrant to design an anti-diversion program that will accomplish this goal. 21 U.S.C. § 823(b)(1) [1970]; 21 C.F.R. § 1301.74(b).

This regime is one of practical necessity. As the DEA has made clear, it is the registrant's responsibility to design and operate a SOM program and to determine whether orders are suspicious. *See* Rafalski Rep., Dkt. # 2000-22 at 17 citing 21 C.F.R. § 1301.74(b) ("The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances."); *Id.* ("The distributor must determine which orders are suspicious . . .," DEA Distributor Initiative Briefings, Ex. 3, US-DEA-00000352 at 360); *id.* at 20, citing December 2007 Rannazzisi Letter (Ex. 2, supra) (emphasizing that it is solely the responsibility of registrants to design and operate a SOM program). Registrants know their business and their customers better than the DEA and hence are best positioned to design the most effective anti-diversion program. It is for this reason that DEA

allow Mr. Rafalski more latitude to testify about his prior DEA experience. Nonetheless, the limitations imposed at the deposition in no way prevented Defendants from learning the bases for Mr. Rafalski's opinions, which he explained in great detail in his report and during his two-day deposition.

regulations do not specify the exact components of an anti-diversion program, and why the DEA does not mandate that registrants put in place any particular program.

Even though the DEA does not mandate specific programs, the agency is able to evaluate the effectiveness of programs designed and operated by registrants and determine whether they meet the requirements of the CSA and the implementing regulations. As a long-time DEA investigator who engaged in precisely this type of investigation, Mr. Rafalski obviously is qualified to undertake this same evaluation in this case.

Based on his extensive experience evaluating SOM programs, Mr. Rafalski identified various components of an effective anti-diversion program, including:

- Utilization of a customer questionnaire that seeks information regarding customers' compliance histories with the state and medical / pharmacy board, their percentage of controlled substance business, identification of other distributors they are obtaining controlled substances from, and the percentage of cash payments they receive;

- Operation of a SOM program that takes into account drug types (with thresholds being more stringent for substances with a higher probability of being targeted for diversion), population (the cumulative amount of controlled substances being distributed by a registrant to a geographic area or region should be monitored to insure it is consistent with legitimate population consumption), and patterns of orders (whether controlled substances are being ordered in combinations of frequently abused drugs);

- A due-diligence program with a person or department specifically identified and responsible for approving threshold quantities, documenting the justification for the increase or decrease of thresholds, appropriately managing the roles of sales staff, conducting and documenting sufficient due diligence prior to shipping an order flagged as suspicious.

Defendants appear to argue that none of these measures are required because they are not specifically enumerated in a DEA regulation. But the point is not whether each and every one of these components is specifically required by law. Based on his experience with the DEA, Mr. Rafalski has quite properly formed the opinion that each of these components is an essential part of an effective system of controls against diversion. Moreover, Mr. Rafalski does not examine these components in

isolation, but rather evaluates each Defendant's SOM program as a whole, through consideration of all of the relevant components together. Notably, Mr. Rafalski did not find sporadic minor technical deviations from the components he identified, but rather wholesale failures to implement most of them.

Because the CSA requires that registrants "maintain effective controls against diversion," measures that are necessary to maintaining effective controls—for example knowing your customer or using available chargeback data—are required under the statutory scheme and hence are "regulatory requirements." As the multitude of DEA administrative enforcement actions against registrants makes clear, *see* Rafalski Rep., Dkt. # 2000-22 at 21-31, registrants can be held liable for failing to implement measures necessary to maintain effective diversion controls, even if such measures are not specified in a DEA regulation. For example, the DEA alleged that Defendant Mallinckrodt's failure to utilize chargeback information amounted to a failure "to maintain effective controls against diversion, including a requirement that [Mallinckrodt] review and monitor these sales and report suspicious orders to the DEA." *See* Ex. 1, AMOA at 1, 3. At the conclusion of the DEA's investigation, and in lieu of an enforcement action against its DEA registrations, Mallinckrodt acknowledged that from January 1, 2008, through January 1, 2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007," and agreed to put into place a system for chargeback data monitoring. *Id.* at 3-5. Hence, even though the regulations did not expressly state that registrants should utilize chargeback data, Mallinckrodt's failure to take into account this rich source of downstream data was actionable precisely because the data would have enabled Mallinckrodt to identify suspicious orders. For this same reason, the measures identified by Mr. Rafalski in his report—the same measures the DEA considers when evaluating SOM programs and which are effective tools for identifying

suspicious orders—are an appropriate basis for Mr. Rafalski to opine that Defendants failed to maintain effective controls against diversion.

2. Mr. Rafalski's Opinion about Subsequent Orders Being Suspicious in the Absence of Due Diligence Is Reasonable and Reliable.

Defendants also challenge two assumptions that Mr. Rafalski asked Dr. McCann to make when applying the various methodologies to the ARCOS data. The first assumption is that Defendants did not perform adequate due diligence, or in many cases any due diligence, prior to shipping a suspicious order ("the no due diligence assumption"). The second assumption is that in the absence of performing such due diligence, a registrant must hold any subsequent orders, regardless of whether those orders would have independently been flagged as suspicious by a suspicious order methodology ("the subsequent order methodology"). Both of these assumptions are reasonable and reliable.

The "no due diligence assumption" is a factual assumption that is well supported by Mr. Rafalski's careful review of Defendants' specific SOM programs. *See* Rafalski Rep., Dkt. # 2000-22 at 46-186. Defendants' motion largely ignores this section of the Rafalski Report and certainly does not argue that these findings lack any basis. Nor could it, given that the evidence supporting these sections come from Defendants' own productions. Notably, Mr. Rafalski considered not only Defendants' failure to produce due diligence files, but also the absurdly trivial number of "suspicious orders" reported by each Defendant to the DEA. The due diligence requirement and the reporting requirement are triggered together by the identification of an order as "suspicious"; it would have been illogical for Mr. Rafalski to assume that Defendants carried out due diligence (for which they have no documentation) on orders they failed to report to the DEA. If a Defendant's algorithm identified the order as calling for due diligence, it would also have called for reporting. *See* 21 C.F.R. § 1301.74 (establishing requirement that registrants design and operate a system to disclose suspicious orders of controlled substances and that the registrant inform DEA of such orders when they are

discovered). The absence of reporting confirms the failure to begin a due diligence examination. Moreover, as Mr. Rafalski documents, Defendants' SOM programs allowed them to ship orders before any due diligence could be carried out. But once an order was shipped, due diligence would serve little purpose. In light of these "ship first, ask questions later" policies, it is Defendants' burden to establish that due diligence nonetheless took place. But, as Mr. Rafalski found, Defendants' files are devoid of any such evidence.

Defendants focus on a red herring, specifically Mr. Rafalski's suggestion that suspicious order reports and due diligence records must be documented and "retained forever" despite the fact that, at least according to Defendants, no such requirement appears in the DEA regulations. This misses the point. Mr. Rafalski's analysis provides *prima facie* evidence that Defendants either failed to perform due diligence, or performed inadequate due diligence on their suspicious orders. In order to rebut this, Defendants should come forward with evidence of the due diligence they purport to have performed. This is the same concept of burden-shifting that is central to the CSA regulatory scheme. *See, e.g.*, *Masters Pharm.*, 861 F.3d at 212-213 (holding that once a distributor has identified a suspicious order it is required to dispel that suspicion by performing due diligence prior to shipping), citing *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,500 (Drug Enf't Admin. July 3, 2007). Thus, the point is not that due diligence materials necessarily need to be retained "forever," but rather that it is reasonable to conclude that an order that is flagged by an appropriate SOM algorithm was suspicious in the absence of documentation evidencing the due diligence that supported its shipment. It is a reasonable assumption that if due diligence wasn't documented, it in fact did not occur.

Defendants take issue with the evidence on which this assumption is based; however, that is a question of weight, not admissibility. Of course, at trial, Defendants will have the opportunity to undercut Mr. Rafalski's assumptions, to try to persuade the jury that their due diligence was robust, and that they would have documents to prove that if they had not destroyed them all based on their

"corporate policies"—policies they apparently they did not suspend even after DEA investigation of registrants' SOM programs (including those of many Defendants) had become commonplace.

At any rate, drawing negative inferences from the failure of Defendants to maintain due diligence files is a reasonable position, confirmed both by the DEA and some of Defendants' own employees.[10] In addition, as Mr. Rafalski emphasizes in his report, documentation of due diligence is important to explain why decisions were made and to inform future decisions regarding flagged orders. A failure to retain due diligence records is thus relevant in assessing a registrant's SOM program and whether it is maintaining adequate controls against diversion.

The subsequent order assumption is also reasonable. As Mr. Rafalski explains, one of the purposes of a SOM program is to investigate customers that have placed suspicious orders to ensure that they are legitimate customers. Indeed, this is the premise behind the DEA's admonishments that registrants must know their customers. Failing to investigate a suspicious order and continuing to ship Schedule II narcotics to that customer notwithstanding its placement of a suspicious order risks "potentially sending larger and larger quantities of controlled substances to a buyer that is already under suspicion of being a diversion risk." Rafalski Rep., Dkt. # 2000-22 at 40. Defendants argue that "Rafalski points to no real-world suspicious order monitoring system that operates like this" and hence is a "method is made for litigation." Rafalski Mot., Dkt. # 1900 at 11-12. But Mr. Rafalski's logic has been endorsed by the DEA in its 30(b)(6) deposition testimony, *as well as by some of the Defendants*. *See* DEA 30(b)(6) (Designee Thomas Prevoznik) Dep. (04/18/19), Dkt. # 1969-13 at 628:24-629:15 (agreeing that if a wholesale distributor gets a flag of a suspicious order, it should block

[10] *See* Rafalski Dep. Dkt. # 1969-18 at 171:8-12; Rafalski Dep. Dkt. # 1969-19 at 518:22-519:3 (testifying that in Mr. Rafalski's experience, under DEA policy and standards if there is no documentation or record of due diligence, it did not occur.); Ex. 4, Shirlene Justus Dep. (07/13/18) (Cardinal Health) at 316:10-317:21 (standard practice and procedure required documenting the reasoning behind clearing orders); Steve Reardon Dep. (11/30/18), Dkt. # 1970-4 (Cardinal Health) at 447:19-448:1 (confirming that the due diligence justifying decisions to ship suspicious orders to a pharmacy should have been documented).

that shipment and terminate all future sales until they can rule out that diversion is occurring); Ex. 5, MCKMDL00409224 at 239 ("Once McKesson deems an order and/or customer suspicious, McKesson is required to act. This means all controlled substance sales to that customer must cease and the DEA must be notified."); Ex. 6, Prevoznik Dep. Exhibit P-8 (Cardinal Health reply brief in *Cardinal Health v. Holder* (D.D.C.) stating "Cardinal Health's policy about which it informed DEA as early as 2009, was that if a customer's order could not be filled because it was suspicious, Cardinal Health would terminate controlled substance sales to the customer and report the termination to the DEA."). Moreover, in *Southwood Pharm., Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007), the DEA made clear that it was investigation of the *customer*, not of an isolated order, that is the heart of effective control against diversion, even if suspicion is triggered by particular orders. Indeed, in that case, the DEA noted that, based on the information Southwood had about certain pharmacies, it should have stopped shipping hydrocodone to them altogether. 72 FR at 36501.

Once again, at any rate, Defendants' disagreement is a question of weight, not admissibility. Defendants are free at trial to argue that there is nothing wrong with continuing to ship opioids to a customer for whom a prior order was flagged as suspicious without first investigating and clearing the flagged order. Plaintiffs do not believe Defendants' position makes any sense, but whether it does or does not is for the trier of fact to determine.

C. The Methodologies Identified by Mr. Rafalski and Used by Dr. McCann Are Reliable

Mr. Rafalski's report identifies five methodologies that may be used to identify suspicious orders (Methodology A-E). Rafalski Rep., Dkt. # 2000-22 at 40-46. All of these methodologies are reliable bases for Mr. Rafalski's opinions because they were either endorsed by the D.C. Circuit or were used by Defendants themselves.

1. Maximum Monthly, Trailing Six-month Threshold

This method identifies transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed the highest number of dosage units shipped by the Distributor to the Pharmacy in any one of the six preceding calendar months.

The method is based on the volume-based portion of the test set forth in *Masters Pharm.,* 861 F.3d at 206. In *Masters*, the D.C. Circuit upheld a DEA decision revoking the registration of Masters, a distributor of controlled substances to pharmacies, where the distributor shipped flagged orders without performing due diligence. The court considered Masters' SOMS Computer Program which flagged orders (or sets of orders) where:

> (a) an order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months;
>
> (b) the pharmacy ordered a controlled medication more frequently in a 30-day period than it had in any of the previous six calendar months; *or*
>
> (c) the pharmacy's ordering pattern for a controlled medication deviated in some other notable way from its ordering pattern over the previous six months.

Id. at 216. The D.C. Circuit concluded that the above methodology for identifying suspicious orders of unusual size was a reliable one, emphasizing that "[a]s a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence." *Id.* The D.C. Circuit also held that, without due diligence, these orders could not legally be shipped. *Id.* at 222-23. Notably, nothing in the court's decision indicated that the above methodology was appropriate for use only by Masters; in fact, the decision focused on the statutory language of the CSA and the methodology's ability to satisfy the statutory command. Given that this methodology was approved by a federal appellate court as an appropriate means for identifying suspicious orders, there is nothing unreliable about applying it generally to a wide range of registrants.

2. Twice Trailing Twelve-Month Average Pharmacy Dosage Units

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a calendar month to exceed twice the trailing twelve-month average dosage units to pharmacies served by the distributor. The method is a variant of Appendix E-3 of the Chemical Handler's Manual ("Appendix E-3"), which is explained below.

3. Three Times Trailing Twelve-Month Average Pharmacy Dosage Units

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a calendar month to exceed three times the trailing twelve-month average dosage units to pharmacies served by the Distributor.

The method is based on Appendix E-3,[11] with some minor adjustments. These guidelines contained in this manual relate to "Listed Chemicals" and are primarily focused on the sale of chemicals used to make illicit methamphetamine. These chemicals are also subject to a separate, and less stringent, suspicious order reporting requirement. In contrast to the suspicious order definition for the more strictly regulated Schedule II and Schedule III controlled substances (which hinges on orders of "unusual" size, pattern, or frequency), the "suspicious orders" of Listed Chemicals are defined by 21 U.S.C. § 830(b)(1)(A) as orders of "extraordinary" size.[12]

Appendix E-3 outlines "a voluntary formula for use by distributors [of Listed Chemicals] to wholesale and retail levels."[13] The formula sets threshold purchase levels based on the last twelve months purchases by the same customer type from the same distribution center (e.g., the customer group).[14] That amount is divided by the total number of customer months (months in which

[11] *See* Ex. 7, U.S. DEP'T OF JUSTICE, DRUG ENF'T ADMIN. CHEMICAL HANDLER'S MANUAL, (Jan. 2004) ("Chemical Handlers Manual, 2004 Edition").

[12] The Chemical Handler's Manual guidelines only address Schedule II and Schedule III controlled substances to the extent those substances also contain Listed Chemicals.

[13] *Id.*

[14] *Id.*

purchases are above zero) and multiplied by a factor to determine the maximum amount a customer may purchase.[15] According to the Manual, the "[f]actor equals 3 for C-II and C-III Controlled Substances **containing List I Chemicals** and 8 for C-III-IV-V Controlled Substances and non-Controlled OTC products **containing List I chemical items**."[16]

A number of distributors used the formula in Appendix E-3 (or some variant of that formula) for all or part of their SOM systems. For example, Cardinal Health's "Process to Establish SOM Threshold Limits"[17] set thresholds by, *inter alia*, differentiating customers through segmentation by size and/or specialty and evaluating historical controlled substance sales data per drug family, per month or each customer segment to establish appropriate threshold limits, using the multiples of 3, 5, or 8.[18] ABDC employed a threshold-based system that applied a multiplier of three to a customer's average purchases.[19] Similarly, Walgreens reported suspicious orders to the DEA from 2007 through 2012 using a version of the formula described in Appendix E-3.[20]

Likewise, a number of manufacturers utilized a system that separated purchasers by class of trade, calculated a historical average and then applied a multiplier of three to trigger flags for suspicious orders. For example, Watson used a multiplier of three for wholesalers.[21] Mallinckrodt originally defined "peculiar orders" as "[o]rders in excess of [redacted] the amount of product ordered during the previous [redacted] by customer, by sku."[22] However, in 2010 Mallinckrodt

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[15] *Id.*

[16] *Id.* (emphasis added).

[17] Ex. 8, CAH_MDL_PRIORPROD_AG_0004208.

[18] *See* Ex. 9, CAH_MDL_PRIORPROD_HOUSE_0003331 at 345 (Board of Directors of Cardinal Health, Inc., *Investigation Report of the Special Demand Committee,* Apr. 12, 2013).

[19] *See* Christopher Zimmerman Dep. (08/03/18), Dkt. # 1972-16 at 121:12-21; 122:18-23.

[20] *See* Ex. 10, Walgreens's Second Supplemental Responses to Plaintiffs' (First) Combined Discovery Requests, No. 3.

[21] Ex. 11, Allergan_MDL_02181128 at 1150 (noting that the "SOMS Multi" for wholesalers was "3").

[22] Ex. 12, MNK-T1_0000263965 at 697 (07/15/08 SOM).

increased its multiplier by defining a "peculiar order" as an "order that meets an internal established criteria of [redacted] the average amount of product ordered during the previous [redacted] months by DEA reporting class."[23]

4. Maximum 8,000 Dosage Units Monthly

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a calendar month to exceed 8,000 dosage units. The method is based on a policy in place at McKesson Corporation. In May 2007, McKesson launched the Lifestyle Drug Monitoring Program (hereinafter "LDMP").[24] The LDMP was limited to four drug products (oxycodone, hydrocodone, alprazolam and phentermine).[25] For these four drugs, an 8,000 monthly dosage unit threshold was set for every customer nationwide.[26]

5. Maximum Daily Dosage Units

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a day to exceed a number of dosage units that varies by drug type and within some drug types by formulation.

The method is based on a policy in place at Cardinal Health from the early 1990s through 2008[27] and is outlined in Cardinal Health's DEA Compliance Manual.[28] Cardinal's manual, under the heading "Required Reports to DEA," states as follows:

> Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined

[23] Ex. 13, MNK-T1_0000264260 (10/29/10 SOM).

[24] Ex. 14, MCKMDL00355251.

[25] *Id.*

[26] *Id.*

[27] *See* Reardon Dep., Dkt. # 1970-4 at 429:3-14.

[28] Ex. 15, CAH_MDL_PRIORPROD_DEA07_01383895.

> averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.
>
> Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.
>
> In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities, and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.[29]

The Dosage Limit Charts contained in Exhibit P are entitled "Excessive Purchases Schedule II" and "Excessive Purchases Schedule III, IV, V" and provide the dosage units Cardinal used to identify transactions pursuant to this methodology.[30]

As the above discussion makes clear, all of these methodologies are reliable methodologies for purposes of withstanding a *Daubert* challenge. The reliability of Methodology A has been confirmed by the D.C. Circuit, the highest and most recent court to evaluate a SOM methodology to date. Variations of the remaining methodologies (Methodologies B-E) *have been used by several of the Defendants themselves* at various times. While Mr. Rafalski declined to endorse Methodologies B-E as appropriate for a SOM program *because they would undercount suspicious orders*, they are certainly reliable methodologies for showing what Defendants would have seen had they actually applied some of the methodologies specified in their own SOM programs. As Defendants incorporated these methodologies into their SOM programs, they cannot now object and claim they are unreliable when Plaintiffs use them.

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[29] *Id.* at 01383939.

[30] *Id.* at 01384160-01384161.

Defendants complain that Methodology A is being used as a "one-size-fits-all" methodology, ignoring the differences between Defendants. McCann Mot., Dkt. # 1783 at 5-6, 10-11. According to Defendants, because the DEA has stated that "the variables that indicate an order is suspicious are very fact intensive and differ from distributor to distributor and from customer to customer," one cannot apply Methodology A (or any uniform methodology) to screen for suspicious orders. Defendants mischaracterizes the DEA's statement. The DEA was explaining why *the agency* could not impose a threshold, and why it was the *duty of the registrants* to develop their own SOM system tailored to their specific factual circumstances.[31] But having failed in that duty, Defendants should not be allowed to avoid liability and responsibility for their failures by now hiding behind the DEA. As explained above, the D.C. Circuit held based on the language of the regulation that the *Masters* approach was a reliable method for identifying suspicious orders of unusual size. *Masters Pharm.,* 861 F.3d at 216 ("orders that deviate from a six-month trend are 'unusual' and not 'normal' occurrence"). The logic of this opinion should not change based upon the identity of the registrant.

Moreover, Mr. Rafalski *does not opine* that Methodology A must have been adopted by any particular Defendant. His opinion is that this method provides "a reasonable estimate and an initial trigger and first step for identifying orders of unusual size" and is one of a number of methodologies that could be used to identify suspicious orders. Rafalski Rep., Dkt. # 2000-22 at 46. It is simply not feasible, or necessary, for Plaintiffs to develop a suspicious order methodology tailored to each Defendant. It is relevant, and helpful to the trier of fact, to see the number of suspicious orders that *each* methodology would have flagged; together, these analyses provide the Court with a reasonable range of the total number of orders each Defendant should have identified as suspicious and investigated. If Defendants truly believed that Methodology A was inappropriate for their business

[31] *See* Ex. 16, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-15-471, PRESCRIPTION DRUGS: MORE DEA INFORMATION ABOUT REGISTRANTS' CONTROLLED SUBSTANCES (2015) at 80-81.

model or unique circumstances, they could have come forward with alternative reasonable methodologies and applied those methodologies to arrive at their own estimates for suspicious orders. Their failure to do so does not render Methodology A unreliable.

Defendants also contend that there is a contradiction between Mr. Rafalski's purported opinion that a large proportion of suspicious orders were diverted and the important role of over-prescription in the opioid epidemic. *See* Rafalski Mot., Dkt. # 1900 at 12. To begin with, Mr. Rafalski is not expressing an opinion on the number of suspicious orders that were actually diverted. More importantly, there is nothing contradictory about identifying both diversion and over-prescribing as causes of the opioid epidemic. Indeed, it is logical that the two causes operated in tandem, with increased shipments from over-prescribing leading to increased opportunities for diversion. In their capacity as registrants under the CSA, Defendants were charged with maintaining effective controls against diversion. That diversion may not have been the sole cause of the epidemic does not in any way diminish Defendants' responsibility for the diversion that occurred and the resulting harms.[32]

The fact that Mr. Rafalski did not independently verify or analyze Dr. McCann's results is irrelevant. Indeed, he lacks the data-analysis expertise to do so. Mr. Rafalski is entitled to rely instead on Dr. McCann's expertise and analysis. Pursuant to Federal Rule of Evidence 703, an expert's testimony may be based on data and conclusions of other experts. *Asad v. Cont'l Airlines, Inc.*, 314 F.Supp.2d 726, 740 (N.D. Ohio 2004); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 675 (6th Cir. 2010); *see also Williams v. Illinois*, 567 U.S.50, 89 (2012) (Breyer, J., concurring) ("Experts . . . regularly rely on

[32] Indeed, it is surely the case that diverted opioids are disproportionately linked with abuse and addiction as compared to over-prescribed opioids. *Every* diverted pill is headed for non-medical use, which Defendants do not dispute is linked to abuse and addiction, *see, e.g.*, Report of Robin Lyerla (05/10/19), Dkt. # 1939-21 at 6; Report of Melanie Rosenblatt (05/10/19), Dkt. # 1939-31 at 46-48, while the percentage of patients prescribed opioids for pain who misuse or abuse their opioids is estimated to range from 21% to 43%, and the percentage of patients prescribed opioids for pain who develop substance use disorders is estimated to range from 8% to 40%. *See generally*, Report of Anna Lembke (03/25/19), Dkt. # 2000-10.

the technical statements and results of other experts to form their own opinions."). Moreover, Defendants have presumably carefully scrutinized Dr. McCann's work. Although they contend that Dr. McCann "ran certain of his algorithms incorrectly," they concede that the errors are not "core flaws" with respect to his analysis. McCann Mot., Dkt. # 1783 at 1. And as explained below, the few issues Defendants have identified are not actually errors at all.

D. Mr. Rafalski is Not Required to Analyze Suspicious Orders or Determine Whether They Were Actually Diverted

Defendants repeatedly criticize Mr. Rafalski for failing to review and opine on specific suspicious orders. This type of review is simply not necessary. Mr. Rafalski's report makes clear that in his opinion the metric identified in *Masters* is "a reasonable estimate and an initial trigger and first step for identifying orders of unusual size." Rafalski Rep., Dkt. # 2000-22 at 40. Thus, the opinion Mr. Rafalski is offering is that, consistent with the *Masters* decision, Defendants were obligated to investigate all suspicious orders, including those identified by Dr. McCann's analysis, prior to shipping them. Defendants failed to adequately identify suspicious orders and to do the requisite investigation prior to shipping. This investigation is required on all flagged orders. Given the focus of his opinion—Defendants' failure to identify suspicious orders in the first place—there was no reason for Mr. Rafalski to determine whether all of the suspicious orders were in fact suspicious and should not have been shipped.

Moreover, it is simply untrue that identifying specific suspicious orders is a necessary pre-requisite to assess a Defendant's SOM program. In fact, Mallinckrodt's own diversion expert, Mr. Ronald Buzzeo, opined that Mallinckrodt's SOM program complied with relevant CSA and regulatory requirements, *without analyzing a single suspicious order*. Mr. Buzzeo explained why this was appropriate:

> Q: And in forming this opinion for the 2012 through 2018 time period, did you review any of the orders that Mallinckrodt actually received and shipped?

> A: When you're looking at the process and the material, you don't have to actually look at orders. Because looking at an individual order or a thousand orders or something is not really going to tell you whether something is suspicious or not.
>
> So you're looking at the process. You have the process in place to look at the orders to make a determination. That's what I looked at. I looked at the regulation. I looked at the guidance letters, industry experience, my experience, to make that determination.

Ex. 17, Ronald Buzzeo Dep. (06/28/19) at 437:15-438:2.

Defendants also criticize Mr. Rafalski for his "opinion" that every single pill contained in every single suspicious order was diverted for unlawful use. This opinion was never offered by Mr. Rafalski and is a strawman concocted by Defendants. When asked by defense counsel to express a view as to whether orders that should not have been shipped were necessarily diverted, Mr. Rafalski responded that the fact that an order was flagged as suspicious made it more probable than not that diversion could occur. The opinions that Mr. Rafalski proposes to offer are, as is required by Rule 26, set forth in his expert Report. Defendants cannot bootstrap testimony they elicited, and then distorted, to create a basis for excluding an opinion Mr. Rafalski has not given.

II. DR. MCCANN'S OPINIONS SHOULD NOT BE EXCLUDED

The bulk of Defendants' challenges to Dr. McCann's opinions do not actually address Dr. McCann's opinions, but rather simply repeat Defendants' attacks of Mr. Rafalski's methodology. It is Mr. Rafalski, with his DEA expertise, who identified the appropriate SOM metrics for Dr. McCann to analyze, and it is Mr. Rafalski, again based on his DEA expertise, who assessed the result of Dr. McCann's analysis. Dr. McCann's role is limited and straightforward: he has the data analysis expertise to apply the metrics identified by Mr. Rafalski to the available data. Defendants offer no serious critique to the computations Dr. McCann made.

A. Dr. McCann Properly Applied Mr. Rafalski's Methodologies

Defendants offer three specific criticisms of Dr. McCann's report. None provides a basis to limit or exclude his testimony:

Specific methodologies: Defendants state that Dr. McCann improperly used a methodology—the Maximum Daily Dosage Units methodology—that was not identified by Mr. Rafalski or discussed in his report. This is incorrect, the Maximum Daily Dosage Unit methodology is extensively discussed Mr. Rafalski's report. Rafalski Rep., Dkt. # 2000-22 at 41, 59-60.

Aggregate flagging: Defendants state that Dr. McCann presented the results of all of his flagging analyses only in the aggregate. This is also incorrect. While Appendix 10 contains charts and tables reflecting the result of applying the five methodologies to each distributor in the aggregate, Plaintiffs provided Defendants with the Excel files used to generate those charts and tables. These Excel files contain every distributor transaction into Cuyahoga and Summit County as well as five columns which indicate whether each transaction passed or failed each of the five methodologies.

National averages: Defendants state that for two of the methodologies ("Exceeding Threshold of Two Times the National Average," and "Exceeding Threshold of Three Times the National Average"), Mr. Rafalski instructed that a national average be used, but Dr. McCann actually used county averages. Dr. McCann used national averages where a Defendant had national averages—but some Defendants do not have a "national" average because they only operate in Ohio and for some time periods (prior to 2006-2014, which is the time period for which the parties have ARCOS data) the only Defendant transactional data available is limited to Cuyahoga and Summit Counties.[33] In these instances, there was no way to calculate a national average, the only average was a state or county average, and its use was not inconsistent with what Mr. Rafalski asked Dr. McCann to do.

[33] Defendants assert that Dr. McCann used county average shipments rather than national average shipments in his illustrative Two-Times and Three-Times examples. (Report of Anupam Jena, Dkt. # 1939-15 at ¶62.) In his expert report and deposition, Dr. McCann discussed using county average shipments and/or national average shipments depending on the availability of nationwide ARCOS data. For some Defendants, including Rite-Aid, the results were inadvertently produced using county average shipments for the entire period, however the impact on identified transactions is *de minimis*.

B. Dr. McCann's Analysis is Clearly Relevant and Will Assist the Trier of Fact

Defendants argue that because there was no legal requirement to use Methodology A, this methodology cannot identify any suspicious orders that Defendants were required to report, and hence Dr. McCann's analysis does not "fit the facts or legal theories in this case." McCann Mot., Dkt. # 1783 at 7. But the fact that a Defendant could have used an alternative to Methodology A does not render Methodology A an unreliable methodology for estimating the magnitude of suspicious orders that any reliable SOM program would have identified. As explained above, Mr. Rafalski, based on his experience evaluating SOM programs and their methodologies, and the D.C. Circuit, agree that Methodology A provides a reliable basis for estimating suspicious orders of unusual size. And Defendants offer no basis, other than sheer speculation, that another "reliable method" would have actually identified a significantly different set of orders. They do not even propose such a method, let alone apply it to ARCOS data to identify any suspicious orders. Given this and the fact that Defendants could potentially have employed other reasonable SOM methodologies, they have failed to establish that Methodology A does not provide a reliable estimate of the suspicious orders of unusual size that they shipped into Cuyahoga and Summit Counties.

Moreover, Defendants are wrong to state that "[n]either McCann, nor Rafalski, nor any other expert witness offers an opinion of the orders they actually claim were suspicious and shipped in violation of applicable legal duties." McCann Mot., Dkt. # 1783 at 8. To the contrary, as set forth in Plaintiffs' Motion for Summary Judgment regarding Defendants' Duties under the Controlled Substances Act, DEA regulations require that, in order to maintain effective controls against diversion, a registrant must design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); report to the DEA suspicious orders "when discovered" (the "reporting duty"); and decline to ship an order identified as suspicious unless, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping

duty"). *See Masters Pharm.*, 861 F.3d at 212-213; *see also Southwood Pharm.*, 72 FR 36487-01, 36500; 21 C.F.R. § 1301.74. Mr. Rafalski's report sets forth his opinion that Defendants violated all of these duties: they failed to maintain adequate SOM systems to identify suspicious orders; they failed to conduct adequate due diligence on orders that should have been flagged as suspicious; and they shipped these orders notwithstanding the lack of due diligence. *See* Rafalski Rep., Dkt. # 2000-22 at §§ IV (reviewing SOM systems of Distributor Defendants) & V (reviewing SOM systems of Manufacturing Defendants).

In short, Mr. Rafalski's evaluations of Defendants' SOM systems, when coupled with Dr. McCann's analysis, are clearly relevant to establishing the magnitude of Defendants' wrongful conduct and the harm it caused. Mr. Rafalski's report establishes that Defendants failed to maintain adequate SOM systems and therefore failed to satisfy their legal obligations under the CSA and applicable regulations. Dr. McCann's data analysis provides an estimate of the suspicious orders that Defendants would have identified had they employed a reliable methodology, including, for example, Methodology A. Taken together, Mr. Rafalski's and Dr. McCann's expert reports establish that Defendants breached their legal duties, provide an estimate of the magnitude of this breach, and are part of Plaintiffs' overall framework of causation and damages in this case.

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' motions to exclude James Rafalski's and Craig McCann's opinions and proposed testimony.

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Respectfully submitted,

/s/*Paul J. Hanly, Jr.*

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